

Remarks

Claims 1, 19, 153, 155-158, and 161 were previously pending and under examination. By this Amendment claims 1, 19, and 153 are currently amended, no claims are currently canceled, and no new claims are added. Remaining claims under current examination are claims 1, 19, 153, 155-158, and 161. No new matter is introduced.

Each of claims 1, 19, and 153 is currently amended to amend “negative charge” in each instance to read as “negatively charged moiety”. Basis for this amendment can be found, for example, at page 20, lines 28-30 of the specification, as already acknowledged by the Examiner on page 3 of the office action.

Rejections Under 35 U.S.C. 112, Second Paragraph

The Examiner indicated that claims 1, 19, 153, 155-158, and 161 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. More particularly, the Examiner on page 2 of the office action asserts that it is not clear if “negative charge” in “[charge motif] composed of [a positively charged free] amino moiety and a negative charge” in claim 1 refers to *net negative charge* of the *entire* charge moiety, or a negatively charged component of a particular chemical moiety [bracketed language restored; emphasis as supplied by the Examiner].

Without meaning to alter the scope of what is claimed, Applicant in response has currently amended claims 1, 19, and 153 to substitute “negatively charged moiety” for “negative charge”. It is respectfully submitted that the amended claim language makes clear that the claimed charge motif is composed of a positively charged free amino moiety and a negatively charged moiety. Claims 155-158 and 161 depend from claim 19 as currently amended. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw his rejection of claims 1, 19, 153, 155-158, and 161 under 35 U.S.C. 112, second paragraph.

Rejections Under 35 U.S.C. 102

Applicant acknowledges that the Examiner has withdrawn the previous rejection of claims 1, 8-10, 14-16, 18-19, 149-151, 154, 158-160, and 162-163 under 35 U.S.C. 102(b) for alleged anticipation by Arnot et al. (U.S. Pat. No. 5,700,906).

Applicant also acknowledges that the Examiner has withdrawn the previous rejection of claims 1, 6, and 8-13 under 35 U.S.C. 102(e) for alleged anticipation by Mayes et al. (U.S. Pat. No. 6,150,459).

The Examiner newly rejected claims 19 and 158 under 35 U.S.C. 102(b) for alleged anticipation by Stanley et al. (U.S. Pat. No. 5,130,417; hereinafter “Stanley et al.”). More particularly, the Examiner asserts on page 4 of the office action that Stanley et al. discloses an immunogenic protein having a molecular weight less than 50 kDa and comprising identical repeating unit Ser-Ser-Asp-Lys-Pro-Asp-Asn which has a positively charged amino moiety (Lys) and a negatively charged moiety (Asp), wherein Lys is separated from Asp by one neutral amino acid residue and wherein the positively charged amino moiety (i.e., Lys ϵ -amine group) in said repeating unit is separated from the positively charged amino moiety (i.e., Lys ϵ -amine group) in the other (adjacent) repeating unit by a distance of at least 8 amino acids.

Claim 19 as currently amended is drawn to a pharmaceutical composition comprising:

an isolated polypeptide of less than 50 kilodaltons *consisting of* identical repeating units, each unit having a charge motif composed of a positively charged free amino moiety and a negatively charged moiety, wherein the positively charged free amino moiety and the negatively charged moiety of each charge motif are separated by at least one neutral amino acid, and wherein the positively charged free amino moiety of one of the charge motifs is separated by a distance of at least 8 amino acids from the positively charged amino moiety of another charge motif, and

a pharmaceutically acceptable carrier. [Emphasis added.]

It should be noted that the polypeptide of the claimed invention *consists of* identical repeating units, as described.

In contrast, it should be noted that the 233-amino-acid-residue-long polypeptide disclosed in Stanley et al. includes, but does not consist of, identical repeating units. The identical repeating units of Stanley et al. can be represented either as Lys-Pro-Glu-Ala-Ser-Ser-Ser-Asp-Lys-Pro-Asp-Asn or as Ser-Ser-Ser-Asp-Lys-Pro-Asp-Asn-Lys-Pro-Glu-Ala. Regardless of how the identical repeating unit of Stanley et al. is represented, the sequence set out in claim 1 of Stanley et al. includes, but does not consist of, four repeats of the above 12-mer sequence. The disclosed four identical repeating units of Stanley et al. thus represent only 48 amino acid residues in a sequence that is 233 amino acid residues long.

Even if the identical repeating unit of Stanley et al. were to be taken as Ser-Ser-Asp-Lys-Pro-Asp-Asn, as suggested by the Examiner, it is immediately evident that the polypeptide disclosed in Stanley et al. merely includes, but does not consist of, repeats of this particular sequence.

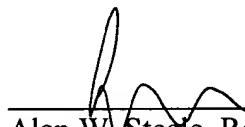
Since the claimed polypeptide *consists of* identical repeating units, whereas the polypeptide of Stanley et al. merely includes identical repeating units, Stanley et al. clearly does not anticipate claim 19. Under this same reasoning, Stanley et al. also does not anticipate claim 158, which depends from claim 19. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 19 and 158 under 35 U.S.C. 102(b) as being allegedly anticipated by Stanley et al.

Summary

Amendments and arguments are presented to overcome rejections made under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 102. For reasons set forth above, the Examiner is urged to withdraw all rejections.

Applicant believes the claims are in condition for allowance. A prompt and favorable action is earnestly solicited.

Respectfully submitted,
Tzianabos, et al., Applicant



Alan W. Steele, Reg. No. 45,128
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210-2211
(617) 646-8000

Docket No.: B0801.70169US00
Date: January 20, 2006
X01/20/06X